MAR 3 2009

# Section 5: 510(k) Summary

The following information is provided as required by 21 CFR § 807.87 for Generic Medical Device's 510(k) premarket notification. In response to the Safe Medical Devices Act of 1990, the following is a summary of the safety and effectiveness information upon which the substantial equivalence determination is based.

**Sponsor:** Generic Medical Devices, Inc. (GMD)
5727 Baker Way NW. Ste. 201
Gig Harbor, WA 98332

**Contact:** Monica Montanez MSRS, RAC, CQA
VP Regulatory Affairs and Quality Assurance
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**Date of Submission:** November 20, 2008

**Proprietary Name:** GMD Universal Sling ™

**Common Name:** Mesh, Surgical, Polymeric

**Regulatory Class:** Class II

**Product Codes:** OTN

**Predicate Device(s):** Gynecare TVT™ Obturator System (K033568), Boston Scientific Lynx™ System (K081275), Caldera Desara ™ (K072456)

**Device Description:**

The GMD Universal Sling System ™ – is a sterile, single use device for the treatment of female stress urinary incontinence. The Universal Sling is comprised of a polypropylene knitted mesh protected by a disposable polyurethane sheath with a disposable low density polypropylene universal sleeve at each end for attachment of the sling to GMD's single use or reusable trocars (sold separately). The universal sleeve has three trocar insertion points, the distal and proximal trocar insertion points are for inside-out / bottom-up approaches and a sleeve end trocar insertion point is for

outside-in / top-down approaches. The method of placement and surgical approach chosen by the physician should be appropriate for the patient's diagnosis and anatomy.

**Intended Use:**

The GMD Universal Sling™ is intended for use in women as a suburethral sling for the treatment of stress urinary incontinence (SUI) resulting from either urethral hypermobility and/or intrinsic sphincter deficiency.

**Comparison to Predicate Devices:**

The GMD Universal Sling has the same intended use and similar technological characteristics as the predicate devices: Gynecare TVT™ Obturator System (K033568), Boston Scientific Lynx™ System (K081275), Caldera Desara ™ (K072456).

**Non-Clinical Studies:**

Bench and animal studies were performed. The data demonstrate that the GMD Universal Sling ™ is substantially equivalent to the predicate device(s).

**Conclusion:**

The GMD Universal Sling ™ has a similar design and the same intended use as the predicates Gynecare TVT™ Obturator System (K033568), Boston Scientific Lynx™ System (K081275), Caldera Desara ™ (K072456). Biocompatibility testing demonstrated the appropriateness of the device materials for the proposed intended use. Bench and animal testing demonstrate that the GMD Universal Sling ™ has similar mechanical and performance characteristics as the predicate device. Therefore, the GMD Universal Sling ™ is substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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SEP 28 2012

Generic Medical Device, Inc.
% Monica Montanez, MSRS, RAC, CQA
VP Regulatory Affairs and Quality Assurance
5727 Baker Way NW, Suite 201
GIG HARBOR WA 98332

Re: K083471
Trade/Device Name: GMD Universal Sling™
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: II
Product Code: OTN
Dated: January 30, 2009
Received: February 3, 2009

Dear Ms. Montanez:

This letter corrects our substantially equivalent letter of March 3, 2009.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

## Section 4: Indications for Use Statement

**510(k) Number:** K083471

**Device Name:** **GMD Universal Sling™**

**Indications for Use:**

The GMD Universal Sling is indicated for use in women as a suburethral sling for the treatment of stress urinary incontinence (SUI) resulting from either urethral hypermobility and/or intrinsic sphincter deficiency.

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Prescription Use ___X____ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

David Krone for MKM 3/3/2009

**(Division Sign-Off)**
**Division of General, Restorative, and Neurological Devices**

**510(k) Number** K083471

Page 1 of __1__